

**Remarks/Arguments:**

The pending claims are 54-84, 93-128. Claims 85-92 have previously been canceled. Claim 128 has been withdrawn from consideration.

Applicants filed a Supplemental Information Disclosure Statement on December 2, 2005 and request an indication that all of the information identified in it has been considered.

Applicants acknowledge with thanks the Examiner's allowance of claims 54-59, 93-100, 102-122. Applicants also acknowledge with thanks the Examiner's indication that claims 62, 63, 68, and 69 would be allowable if rewritten in independent form.

With regard to the foregoing, the Examiner is invited to consider the following points:

- (1) Applicants believe that claims 62 and 63 should be allowed (as opposed to merely allowable if rewritten in independent form) because they depend from allowed claim 54.
- (2) Applicants also believe that claim 68 should be allowed (as opposed to merely allowable if rewritten in independent form) because it is already an independent claim.
- (3) Applicants also note that section 5 of the Office Action Summary and paragraph 9 of the Detailed Action states that claim 101 has been allowed. But section 6 of the Office Action Summary and paragraph 4 of the Detailed Action are inconsistent and state that claim 101 has been rejected under 35 U.S.C. § 112.

Clarification regarding the foregoing points is respectfully requested.

**I. Rejection Of Claims 71-84, 101, 123-127 Under 35 U.S.C. § 112, First Paragraph**

In paragraph 4 of the Office Action, claims 71-84, 101, and 123-127 have been rejected under 35 U.S.C. § 112, first paragraph. The Office Action contends that the following subject matter is not described in the specification: "a plurality of separate spaced apart wires," "wires with two opposing ends being joined together," and "the wire structure is interwoven with the graft."

To comply with the written description requirement of 35 U.S.C. 112, para. 1, . . . each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. MPEP 2163(b)

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. MPEP 2163.04.

Applicants respectfully disagree with the § 112 rejection for the reasons set forth below.

**A. a plurality of separate spaced apart wires**

Page 3 of the Office Action contends that the specification does not disclose "a plurality of separate spaced apart wires." According to the Office Action, the specification discloses a stent formed by a wire around a mandrel to form a zig-zag pattern and hoops but not a

plurality of wires. Applicants respectfully disagree.

The phrase "a plurality of separate spaced apart wires" is recited in claims 71 and 123.

Claim 71 recites:

The graft as defined in claim 70, wherein said primary graft body is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires.

As described in the specification, at least one embodiment of the invention does have "a plurality of separate spaced apart wires" as illustrated at least by the following passages:

A bifurcated stent in accordance with the present invention which is indicated at 10 in FIG. 1a comprises a wire skeleton which is constructed in four separate parts, namely a proximal part 12, a first frustoconical part 14, a first distal part 16 and a second frustoconical part 18. (page 22, lines 17-22) (emphasis added)

\* \* \* \* \*

Each of the four parts of the bifurcated stent 10 is made in substantially the same way by winding a shape memory nitinol wire, typically nitinol type M wire, onto a mandrel 46. (page 23, lines 7-10)

\* \* \* \* \*

The first and second frustoconical parts 14, 18 are secured to the distal end 26 of the proximal part 12 of the stent 10 in transversely spaced relation as shown in FIG. 1a by securing the apices 22 of the hoop 20 forming the wider proximal end 30 of each of the frustoconical parts 14, 18 to juxtaposed apices 22 of the hoop 20 on the distal end 26 of the proximal part 12. (page 26, lines 11-18)

\* \* \* \* \*

The proximal end 34 of the distal part 16 is secured to the narrower distal end 32 of the first frustoconical part 14 by tying each apex 22 on the proximal end 34 of the first distal part 16 to a juxtaposed apex on the distal end 32 of the first frustoconical part 14. . . . (page 26, line 25-page 27, line 1)

\* \* \* \* \*

The second stent 40 includes a wire skeleton comprising a proximal frustconical part 42 and a distal part 44. . . The frustoconical proximal part 42 is constructed in the same way as the frustoconical parts 14, 18 of the bifurcated stent 10; the distal part 44 is constructed in the same way as the distal part 16 of the bifurcated stent 10. The distal end of the frustoconical proximal part 42 is secured to the proximal end of the distal part 44 by securing juxtaposed apices using polypropylene filaments as described above. (page 29, lines 8-21)

Referring to Figs. 1A and 6 as well as the above-quoted portions of the specification, the specification therefore discloses at least a primary graft body comprising the combination 80, 86 circumferentially reinforced by separate spaced apart wires forming parts 16, 42, 44.

Accordingly, applicants request that this rejection of claim 71 (and claims depending therefrom) be withdrawn. It is noted that rejected claims 75-78, 80, 82-84 do not depend from claim 71 and do not include the recitation of "a plurality of separate spaced apart wires". Instead, claims 75-78, 80, 82-84 depend from claim 70. Accordingly, applicants request that the § 112 rejection of claims 75-78, 80, 82-84 be withdrawn, thereby placing them in condition for allowance.

Claim 123 recites, in part:

An intraluminal graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires . . .

Referring to Figs. 1A, 1B, and 5-7, along with the above-quoted portions of the specification, the specification discloses, for example, separate spaced apart wires in parts 12 and 16, parts 18 and 16, parts 12 and 42, and parts 12 and 44.

Accordingly, applicants request that this § 112 rejection of claim 123 (and the corresponding dependent claims) be withdrawn.

B. wires with two opposing ends being joined together

The Office Action contends that the specification does not disclose "wires with two opposing ends being joined together." The Office Action contends that "[t]he specification discloses only one wire and does not disclose ends of the wire are joined together." Applicants disagree.

The phrase "ends being joined together" is recited in claims 72 and 76.

Claim 72 recites:

The graft as defined in claim 71, wherein each of said separate spaced apart wires comprises two opposing ends, said ends being joined together on the outside of said primary graft body.

Claim 76 recites:

The graft as defined in claim 75, wherein each of said separate wires comprise two opposing ends, said ends being joined together on the outside surface of said supplemental graft body.

As explained and illustrated above, at least one embodiment described in the specification includes a plurality of wires. Fig. 4A is a side view of part 16, for example. (col. 7, lines 58-60; col. 10, lines 18-22). The upper left end of the stent in Fig. 4A is connected to the

lower right end (e.g., via the interconnecting single wire, via securing means 99, via a graft layer, or some combination thereof). Furthermore, since "the graft layer may be disposed internally of the stent" according to an exemplary embodiment (col. 5, lines 5-6), the specification supports the recitations in claims 72 and 76 that the ends are joined together on the outside surface of the primary graft body.

Accordingly, applicants request that this § 112 rejection of claims 72 and 76 on this basis be withdrawn.

C. the wire structure is interwoven with the graft

The statement on page 3 of the Office Action explaining the basis for this rejection is an incomplete sentence. It states:

"the wire structure is interwoven with the graft." The specification discloses the stent

Applicants thank the Examiner for the courtesies extended applicants' representative on September 23, 2005 during which this rejection was discussed. During that discussion, the Examiner stated that the complete sentence should read:

"the wire structure is interwoven with the graft." The specification discloses the stent but does not show it interwoven with the graft.

Applicants respectfully disagree.

Claim 101 recites:

The graft of claim 94 wherein the wire structure is interwoven with the surface of the respective graft body.

Claim 126 recites:

An intraluminal graft as claimed in claim 123 in which wires are interwoven with the graft body.

The specification discloses at least the following:

In some embodiments the graft layer may be secured to the stent by loop elements such, for example, as loops of polypropylene. (page 12, lines 11-13)

The tubular fabric layers may be attached to the proximal and distal parts 12, 16 of the stent 10 by stitching with, for example, 0.003" polypropylene filaments around the apices 22 of the underlying skeleton. (page 27, lines 8-12)

Fabric portion 403 is attached at its proximal and distal ends to the proximal and distal stent portions, respectively, by stitching, for example, with 0.003 inch polypropylene filaments around apices 22 of the stent portions. (page 45, lines 18-22)

The term "interwoven" or "interweave" encompasses a broad range of structures, including exemplary structures disclosed by applicants. For example, the term "interweave" means "to intermix or unite in texture or construction" (Webster's New Universal Unabridged Dictionary, Deluxe Second Edition (New World Dictionaries/Simon and Schuster 1979)) or "to connect closely or intricately" (Webster's New World Dictionary of the American Language, Second Edition (Simon & Schuster 1985)). As shown above, according to one or more of the disclosed exemplary embodiments of the invention, the graft is described, for example, as being secured to the stent, as being attached to parts of the stent by stitching, and as being attached to portions of the stent. Each of these modes of attachment fall within the scope of the term "interwoven" because the stent and the graft of the cited embodiments are united in construction and are connected closely and intricately.

As quoted above from MPEP 2163(b), each claim limitation need only be expressly, implicitly, or inherently supported in the originally filed disclosure. Here, the claim limitation "interwoven" is expressly supported by the disclosure in that the stent and the graft are united in construction and are connected closely and intricately. In view of the foregoing explanation of support in applicants' specification, it is respectfully submitted that the USPTO has not overcome the presumption of specification support as required by MPEP 2163.04.

Accordingly, applicants request that this § 112 rejection of claims 101 and 126 on this basis be withdrawn.

In view of all of the above citations to applicants' specification, applicants request that all of the Section 112 rejections be withdrawn.

## **II. Rejection of Claims 60, 61, 64-67 and 70 Based Upon Double Patenting**

Claims 60, 61, 64-67, and 70 have been rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent No. 5,609,627.

Claims 64-66 depend from allowed claim 54. Accordingly, applicants respectfully request the Examiner's reconsideration of the double patenting rejection of claims 64-66.

Upon notification that this application is otherwise allowable, applicants will submit a terminal disclaimer to overcome the then pending double patenting rejection.

## **III. Interference**

Rule 41.202 provides that an applicant "may" suggest an interference and, if the applicant elects to make such a suggestion, must comply with the requirements listed in that Rule. Applicants will consider the filing of such a suggestion.

**IV. Conclusion**

For all of the above reasons, and in view of applicants' prospective submission of a terminal disclaimer, applicants respectfully submit that all pending claims are allowable.

Respectfully submitted,



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